Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SHAWN O'LIN BARNEY, DENNIS M. LAMBERT, and STEPHEN R. PETTEWAY,

Appeal No. 2003-0912
Application No. 08/487,355

ON BRIEF

Before WINTERS, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 17 and 20-55, which are all of the claims pending in this application.

Claim 17 is illustrative of the claims on appeal and reads as set forth in the Appendix to the Appeal Brief, attached.

No prior art references are relied upon by the examiner.

Grounds of Rejection

Claims 17 and 20-55[1] stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

We reverse this rejection.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

The pending claims are directed to a method for the inhibition of transmission of a hepatitis B virus to a cell, comprising contacting the cell with an effective

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[1] We note on page 2 of the Answer, the examiner indicates that claims 17 and 20-55 stand or fall together. However the rejection of the claims under 35 U.S.C. § 112, first paragraph on page 3 of the Answer is indicated to address claims 17 and 20-50. It would appear from the record that it is a typographical error that claims 51-55 were not included in this rejection. Finding no prejudice to appellants, for purposes of this appeal we treat the rejection of the claims under 35 U.S.C. § 112, first paragraph, as applied to claims 17, and 20-55.

concentration of a peptide having one of 35 peptide formulas set forth in the claim. See Appendix to the Appeal Brief. The peptides correspond to amino acids 638 to 673 of the HIV-1_{LAI} transmembrane protein (TM) gp41, and portions or analogs of DP178 which exhibit anti-membrane fusion capability, antiviral activity, such as the ability to inhibit HIV transmission to uninfected CD-4+ cells, or an ability to modulate intracellular processes involving coiled-coil peptide structures. Specification, page 1. The invention also relates to peptides analogous to DP107 corresponding to amino acids 558-595 of the HIV-1_{LAI} transmembrane protein (TM) gp41. Id.

According to the specification, DP178 and DP107 analogs are recognized or identified by utilizing one or more of the 107x178x4, ALLMOTI5 or PLZIP computer assisted search strategies to identify additional peptide regions which are predicted to have structural and/or amino acid sequence features similar to those of DP107 and DP178. The specification indicates that computer assisted search strategies identified analogous regions similar to DP107 and DP178 in the hepatitis B virus. Specification, pages 54 and 390. The specification provides methodology for hepatitis B inhibition testing. Specification, pages 334, 390-391.

35 U.S.C. § 112

Claims 17 and 20-55 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention.

Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

In order to establish a prima facie case of lack of enablement, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). See also In re Morehouse, 545 F2d 162, 192 USPQ 29 (CCPA 1976).

Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

unpredictability of the art, and (8) the breadth of the claims. (footnote omitted). In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

According to the examiner, "Applicant[s] has [sic] shown that some particular peptides from a few examples can have some effect. This cannot be extended broadly to any peptide from any virus. The mechanism of infection from each of the many possible viruses that can be included in the search motif is so broad that one would have to engage in an undue amount of experimentation to find particular peptides from particular viruses that would have the desired effect. There is no guidance in the specification as to which proteins or peptides that are included in the immense number of peptides which fall within the search motifs that would inhibit viral infection." Answer, page 3.

The examiner finds that "the only antiviral activity taught in the specification is for inhibiting cell fusion between uninfected and infected cells [is] *in vitro* by direct treatment with a peptide." Answer, page 4. The examiner concludes that even assuming arguendo that "one would expect a given hepatis B peptide to have an antiviral effect, the specification is not enabling for methods of 'inhibiting transmission' or 'neutralizing hepatitis B virus.'" Answer, page 4. Finally, the examiner argues that "there is no evidence that an immune response, if induced would have an antiviral effect." Answer, page 5. Thus, according to the examiner, the specification is not

enabled for the scope of the claimed invention. Id.

In spite of the above argument, the examiner also confusingly indicates that "[t]he specification, while enabled for *in vitro* methods, is not enabled for *in vivo* methods even if one were to have an expectation of success that a given hepatitis B peptide will have an antiviral effect." Answer, page 4. Thus, the examiner argues the specification is merely not enabled for *in vivo* uses. Answer, page 5.

Appellants respond, acknowledging that the examiner has indicated that the specification is enabled for *in vitro* uses but is not enabled for *in vivo* uses. Brief, pages 3-4. The appellants argue that the *in vitro* cell fusion assays in section 22 of the specification "predict anti-HEP-B activity of the same peptides (i.e., of the DP178- and DP107-like hepatitis B proteins recited in claim 17) *in vivo*, including the inhibition of transmission of hepatitis B virus to cells." Brief, pages 4-5.

Upon review of the record before us we find that the examiner has not provided sufficient evidence to support a prima facie case of lack of enablement. To begin, the examiner has failed to carefully address the Forman factors as they relate to the issue of lack of enablement of the pending claims. The examiner has failed to indicate why one of ordinary skill in the art would doubt the objective enablement provided for in the specification. Moreover, the examiner has failed to clearly explain how the specification is enabled for *in vitro* uses but not *in vivo* uses. In addition, the examiner has failed to provide sufficient evidence to support his position of unpredictability in the art, lack of correlation between in vitro and in vivo test results, and differences between RNA and

DNA viruses. Answer, page 6. Patent examiners, in relying on what they assert to be general knowledge to negate patentability, must articulate that knowledge and place it of record. Failure to do so is not consistent with either effective administrative procedure or effective judicial review. See In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). In the present case, the examiner has failed to support his conclusion of lack of enablement of the pending claims with sufficient evidence with consideration of the Forman factors relevant to enablement.

This board functions as a board of review, not a de novo examination tribunal. 35 U.S.C. § 6(b) ("The [board] shall . . . review adverse decisions of examiners upon applications for patents . . .."). On this record, we are constrained to find that the examiner has not provided sufficient evidence to support a prima facie case of lack of enablement.

The rejection of claims 17 and 20-55 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is reversed.

CONCLUSION

The rejection of claims 17 and 20-55 under 35 U.S.C. § 112, first paragraph, for lack of enablement is reversed.

REVERSED

SHERMAN D. WINTERS
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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